



DEPARTMENT OF HEALTH & HUMAN SERVICES

777
Public Health Service
Food and Drug Administration

11/9/98
Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

January 5, 1998

Ref: 98-DAL-WL-13

WARNING LETTER

VIA FEDERAL EXPRESS
AND FACSIMILE

Mr. Arthur W. Huguley IV, President
Westway Trading Corporation
Molasses Products Division
365 Canal Street
Suite 2200
New Orleans, Louisiana 70130

Dear Mr. Huguley:

An inspection of your medicated feed mill located at 300 93rd Street, Houston, Texas, conducted by Food and Drug Administration investigators on November 13 and 14, 1997, found significant deviations from Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds (Title 21, Code of Federal Regulations (CFR), Part 225.) Such deviations cause medicated feeds being manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

Observations include, but are not limited to the following:

1. Failure to conduct a thorough follow-up investigation to determine the cause or reason for two out-of-specification assays for a liquid feed supplement containing lasalocid and failure to implement controls to prevent their recurrence.
2. Batch Sheet, Theoretical Usage Calculation, and Theoretical Usage/Actual Usage Reconciliation records do not reflect the lot number of the drug ingredient used in the production of medicated feeds.
3. Failure to document the actual mixing times of the medicated feed batches.

4. Batch production records are not reviewed, dated, and signed or initialed by a responsible person to ensure all production steps were performed.
5. Master production records are not checked, signed or initialed by a qualified individual.

The above is not intended to be an all-inclusive list of CGMP violations. As a manufacturer of medicated and non-medicated feeds, you are responsible for assuring that your overall operations and the products you manufacture and distribute are in compliance with the law.

At the conclusion of the inspection a Form FDA-483, Inspectional Observations, was issued to and discussed with Mr. James Culver, Production Manager. This form is a comprehensive listing of the investigators' observations of deviations found during the inspection. A copy is enclosed for your information.

You should take prompt action to correct these CGMP violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these CGMP violations, may result in regulatory and/or administrative sanctions. The sanctions include, but are not limited to seizure, injunction, and/or notice of opportunity for a hearing on a proposal to withdraw approval of your license, under Section 512(m)(4)(B)(ii) of the Act and 21 CFR 514.115(c)(2). This letter constitutes official notification under the law.

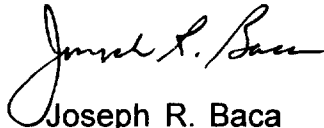
Based on the results of the November 13 and 14, 1997 inspection, evaluated together with the evidence before FDA when your license was approved, the methods used in or the facilities and controls used for, the manufacturer, processing, and packing of medicated feeds are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drugs therein. This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies.

You should notify this office in writing within 15 working days of receipt of this letter, of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the CGMP violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Page 3 - Mr. Arthur W. Huguley IV, President
January 5, 1998

Your reply should be addressed to Reynaldo R. Rodriguez, Jr., Compliance Officer, at the above letterhead address.

Sincerely,

A handwritten signature in black ink, appearing to read "Joseph R. Baca". The signature is fluid and cursive, with the first name "Joseph" being the most prominent.

Joseph R. Baca
Dallas District Director

Enclosure - FDA-483

JRB:RRR:jab

cc: Mr. Joe Harris, Ph.D.
Vice President of Nutrition
and Research Development
Westway Trading Corporation
Molasses Products Division
14015 Park Drive, Suite 217
Tomball, Texas 77375